REMARKS

Status of Claims

Applicants thank Examiner Schultz for the consideration given to the present application. Claims 11-17 and 19-32 are currently pending in this application. Claims 16, 19-22, 24, 25, 28, 29, and 32 are withdrawn from consideration. Claims 1-10 and 18 have been cancelled without admission or prejudice. Thus, claims 11-15, 17, 23, 26-27, and 30-31 are currently subject to examination.

Claims 22, 24-25 and 30-32 are cancelled herein without admission or prejudice. Claims 11, 17, 19-21, and 23 are amended herein. Support for these amendments is found generally in the claims and in the Specification as originally filed; for example, support is found in claims 11, 17, and 30-31 and in the Specification at Page 43, paragraph [0398]; Page 43, paragraph [0399]; Page 45, paragraph [0416]; and Page 45, paragraph [0419] of the published application. New claims 33-38 have been added herein. Support for new claims 33-38 is found in the Specification as originally filed; for example, support for these claims is found in the Specification at Page 43, paragraph [0399]; Page 43, paragraph [0402]; Page 45, paragraph [0416]; and Page 45, paragraph [0419] of the published application. Thus, it is believed that no new matter has been entered.

Election/Restrictions

The Examiner acknowledged Applicants' election without traverse of Group 4, claims 11-17 and 19-32 and the election of the species "polyhydroxylamidoamines". With regard to Applicants' election with traverse of reperfusion disorder in ischemic disease on the ground that the amendment provides to the claims a technical features that Morishita does not teach, the Examiner asserted that the amended claims are not considered free of the prior art. However, the Examiner asserted that upon notice of allowable subject matter, rejoinder will occur in regards to those inventions that fall within the scope of the allowed subject matter. The Examiner made this restriction final.

With regard to Applicants' assertion that the election of "reperfusion disorder in ischemic disease" should be examined with regard to claims 17, 23, 26, and 27 in addition to 11-15 since claims 17 and 23 recite "reperfusion injuries after ischemia" and since claims 26 and 27 recite,

respectively, "ischemic-reperfused myocardium" and "ischemic-reperfused brain." The Examiner asserted that these claims are rejoined since all of the claimed conditions derive from ischemia.

Sequence Compliance

The Examiner stated that the application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§ 1.821(a)(1) and (a)(2). Further, the Examiner stated that the application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 because at least page 128 of the Specification discloses several nucleotide sequences in excess of 10 nucleotides that are not accompanied by a SEQ ID NO.

In response, paragraphs [0367] and [0419] (with reference to the published application) of the Specification have been amended herein to provide proper SEQ ID NOs for the nucleotide sequences in excess of 10 nucleotides. Thus, Applicants submit that the application is in compliance with 37 CFR §§ 1.821(a)(1) and (a)(2).

Claim Rejections - 35 U.S.C. § 102

Claims 11-15, 17, 23, 26, and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Morishita et al. (U.S. Pat. No. 6,262,033). Specifically, the Examiner stated that Morishita et al. disclose treating NF-κB-associated diseases, including ischemic disease, and that Morishita et al. also disclose pharmaceutical compositions containing NF-κB decoys which may be provided in liposomes. The Examiner asserted that the term "polymeric" is broadly defined and is considered to include any type of polymer such as those found in liposomes.

Applicants respectfully traverse these assertions. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).)

To expedite prosecution, independent claims 11 and 17 have been amended herein to further define the NF-κB chromosomal binding site decoy. Specifically, independent claims 11 and 17 have been amended herein to recite, *inter alia*, a method for treatment of NF-κB-associated diseases which comprises administering to an animal an effective amount of a

concatemerized NF-κB chromosomal binding site decoy, wherein the ***concatemerized decoy*** comprises ***two or more end-to-end repeated copies of a domain***, wherein each of the domains comprises a nucleotide sequence that acts as a NF-κB binding site decoy, wherein the ***concatemerized*** decoy is delivered by a polymeric vector, wherein the polymeric vector is selected from the group consisting of ***polyhydroxylamidoamines, cyclodextrin-based dendritic macromolecules, 1,3-dipolar addition polymers,*** and ***carbohydrate-containing biodegradable polyesters***. Support for these amendments is found generally in the Specification as originally filed; for example, support for these amendments is found at Page 43, paragraph [0398]; Page 43, paragraph [0399]; Page 45, paragraph [0416]; and Page 45, paragraph [0419] of the published application. Thus, it is believed that no new matter has been entered.

Applicants submit that Morishita et al. fail to disclose each and every limitation recited in independent claims 11 and 17. Specifically, Applicants submit that Morishita et al. fail to disclose a method for treatment of NF-κB-associated diseases which comprises administering to an animal an effective amount of a ***concatemerized*** NF-κB chromosomal binding site decoy, wherein the ***concatemerized decoy*** comprises ***two or more end-to-end repeated copies of a domain***, wherein each of the domains comprises a nucleotide sequence that acts as a NF-κB binding site decoy, wherein the ***concatemerized decoy*** is delivered by a polymeric vector, wherein the polymeric vector is selected from the group consisting of ***polyhydroxylamidoamines, cyclodextrin-based dendritic macromolecules, 1,3-dipolar addition polymers,*** and ***carbohydrate-containing biodegradable polyesters***.

Rather, Morishita et al. disclose that, "[a]s preferred examples of said NF-κB decoy, there can be mentioned ***oligonucleotides*** containing ***the nucleotide sequence of GGGATTTCCC*** . . . or its complimentary sequence, muteins thereof, and compounds containing any of them within the molecule." (*See* Column 2, lines 21-26, emphasis added). Although Morishita et al. also disclose that, "[t]he more preferred NF-κB decoy includes double-stranded oligonucleotides each containing one or a plurality of the above nucleotide sequence and variants thereof," (*see* column 2, lines 36-38), the working examples of Morishita et al. are ***limited*** to comparatively short oligonucleotides having 20 nucleotides. (*See* Column 5, lines 2-7 & Column 7, lines 1-49). Additionally, the working examples of Morishita et al. are limited to oligonucleotides having, at most, ***one*** of the nucleotide sequence of GGGATTTCCC or ***one*** of its complimentary sequence. (*See* Column 5, lines 2-7 & Column 7, lines 1-49). Moreover, Applicants submit that Morishita

et al. are void of any disclosure concerning concatemerized decoys comprising ***two or more end-to-end repeated copies of a domain***.

Morishita et al. also fail to disclose a polymeric vector selected from the group consisting of ***polyhydroxylamidoamines, cyclodextrin-based dendritic macromolecules, 1,3-dipolar addition polymers,*** and ***carbohydrate-containing biodegradable polyesters***. Rather, Morishita et al. disclose that, "[p]articularly when a nucleic acid or a modification product thereof is used as the NF-κB decoy, the preferred dosage form includes those which are generally used in gene therapy, such as ***liposomes*** inclusive of membrane fusion liposomes utilizing Sendai virus and liposomes utilizing endocytosis, preparations containing cationic lipids such as Lipofectamine (Life Tech Oriental) or ***virosomes*** utilizing a retrovirus vector, adenovirus vector, or the like," and also disclose that, "[p]articularly preferred are membrane fusion ***liposomes***." (*See* Column 3, lines 15-21, emphasis added).

For these reasons, Applicants respectfully request the withdrawal of the rejection of independent claims 11 and 17 as amended under 35 U.S.C. § 102(b). Additionally, as claims 12-15, 23, 26, and 27 depend from independent claims 11 and 17, Applicants also respectfully request the withdrawal of the rejection of these claims under 35 U.S.C. § 102(b).

Claim Rejections - 35 U.S.C. § 103

Claims 11-15, 17, 23, 26, 27, 30, and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Reineke et al. (PMSE Preprints, Sept. 2003. 89: 53-54), in view of Morishita et al. Specifically, the Examiner asserted that Morishita et al. disclose the need for delivery compositions comprising a decoy, and list numerous examples of such compositions including polymeric delivery vehicles as discussed above in the rejection under 35 U.S.C. § 102(b). While the Examiner admitted that Morishita et al. fail to teach that the polymeric vector is a polyhydroxylamidoamine, the Examiner asserted that Reineke et al. disclose specific polyhydroxylamidoamines identical to those recited in the claimed invention and their use in gene and DNA delivery agents. Accordingly, the Examiner asserted that one of ordinary skill would have considered the compounds of Reineke to be useful in delivering the decoy oligos of Morishita et al.

Applicants respectfully traverse these assertions. To advance prosecution, Applicants have submitted a signed declaration under 37 CFR § 1.132, asserting that Reineke et al. describe

the Applicant's own work. Reineke et al. was cited as a reference under 35 U.S.C. § 103. The MPEP discloses that, "[u]nless it is a statutory bar, a rejection based on a publication may be overcome by a showing that it was published either by applicant himself/herself or on his/her behalf." *See* MPEP § 715.01(c). When a claim of an application is rejected, "the applicant may overcome the rejection by filing a specific affidavit or declaration under 37 CFR 1.132 establishing that the article is describing the applicant's own work." *See* MPEP §715.01(c).

The present application filed April 21, 2008, claims the priority benefit of PCT Application No. PCT/US04/42948, filed December 20, 2004, which claims the priority benefit of U.S. Provisional Patent Application Serial Nos.: 60/531,399, filed December 19, 2003, and 60/574,131, filed May 25, 2004. Reineke et al. bear a publication date of September 2003. As a result, Applicants submit that the publication date of Reineke et al. is not more than one year prior to the priority date of the application, and, therefore, does not constitute a statutory bar.

Additionally, as shown in the signed 37 CFR § 1.132 declaration from the inventor, Theresa M. Reineke, it is clear that Theresa M. Reineke is a joint inventor and that the co-author cited in Reineke et al. was merely working under her direction. Thus, Applicants submit that the declarations under 37 CFR § 1.132 are sufficient to remove the Reineke et al. printed publication as a reference under 35 U.S.C. § 103.

Accordingly, it is respectfully requested that the Reineke et al. reference be withdrawn from the above rejections as it is not a proper reference under 35 U.S.C. § 103. Since Reineke et al. was narrowly cited as disclosing polyhdroxylamidoamines (which are recited in dependent claims 30 and 31), and dependent claims 30 and 31 were not rejected over Morishita et al. alone, Applicants respectfully submit that the rejection of these claims under 35 U.S.C. § 103 is moot and should be withdrawn.

Double Patenting

Claims 11-15, 17, 23, 26, 27, 30, and 31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 11, 12, 16-20, 22-26, 28, 29, 57-65, and 70-74 of copending Application No. 10/596,522.

Claims 11-15, 17, 23, 26, 27, 30, and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 12/134,556.

Claims 11-15, 17, 23, 26, 27, 30 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 and 19-29 of copending Application No. 10/596,516.

Applicants maintain that the instant claims are patentably distinguishable over the references in combination or alone. However, in order to expedite prosecution and allowance, a terminal disclaimer has been filed with this Amendment along with payment of the appropriate fee in accordance with 37 C.F.R. § 1.20(d). Accordingly, the double patenting rejection has been overcome and reconsideration is respectfully requested.

CONCLUSION

It is believed that the above represents a complete response to the Office Action dated December 21, 2010. In light of the foregoing, Applicants respectfully submit that the application is in condition for allowance. It is believed that no additional fees are required, but in the event this is incorrect, the Director is authorized to charge any fees which may be required in connection with the present Amendment, or credit any overpayment, to Deposit Account No. 04-1133. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,
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